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10/661,406	09/12/2003	Patrick P. Wu	ENDOS 64190	6647

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EXAMINER
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HOUSTON, ELIZABETH

ART UNIT	PAPER NUMBER
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3731

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/661,406

Applicant(s)

WU ET AL.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,4,6-9,13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,4,6-9,13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***35 USC § 112 Sixth Paragraph***

1. It is assumed that applicant has intended to invoke 112 sixth paragraph as per the means for language set forth in the claims.
  - a. In Claim 4, "means for evacuating air" is interpreted by the specification to be openings in the inner catheter or equivalents thereof.
  - b. In Claim 11, "means for preventing unintentional movement of the gear rack" is interpreted by the specification to be a locking arm or equivalents thereof
  - c. In claim 12 and 14, "means for allowing motion of the gear rack in only one direction" is interpreted by the specification to be a spring or equivalents thereof.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
3. **Claims 13, 15 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilson et al. (WO99/49808) in view of Failla et al. (USPN 5,501,654).**

4. Gilson discloses a system for delivering and deploying a medical device within a patient (see entire document, specifically Figures 9a-9d), the system comprising a delivery catheter including an inner catheter member (10) having a region for mounting the medical device (11) thereon and an outer restraining member (20) co-axially disposed over the inner catheter member and the medical device. The outer restraining member is adapted for axial movement with respect to the inner catheter member (Figs. 1 and 3). A control handle (Fig. 9) has a rotatable thumbwheel (41) connected to a retraction mechanism (40) and the inner catheter member has a proximal end attached to the control handle and the outer restraining member having a proximal end attached to the retraction mechanism (P 10, L 26-29). Rotation of the thumbwheel causes linear movement of the retraction mechanism to proximally retract the outer restraining member sheath to uncover the medical device while the inner catheter member remains stationary (P 10, L 20 – P 11, L 16).

5. Gilson does not disclose that the thumbwheel rotates about an axis of rotation, which is substantially perpendicular to the linear movement of the retraction mechanism.

6. Failla discloses a medical device with a control handle that incorporates the rotation of a thumbwheel to cause proximal linear movement of a retraction mechanism. Failla discloses that the thumbwheel rotates about an axis of rotation, which is substantially perpendicular to the linear movement of the retraction mechanism. The thumbwheel is connected to a retraction mechanism that includes a gear rack (44) and an actuating gear (52). Failla discloses a stop means to prevent movement of the gear

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rack (59) and means for allowing motion of the gear rack in only one direction within the channel (58) (Col 7, line 13-23).

7. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an alternative thumbwheel such as is disclosed in Failla. It is known that it is more a more comfortable and natural movement for a user to move the thumb to rotate the wheel in an up and down direction (parallel to the longitudinal axis) as opposed to right and left direction.

8. Gilson in view of Failla discloses means for allowing motion of the gear rack in only one direction (58) which contacts the distal surface of the gears of the thumbwheel gear but does not disclose that the means for allowing motion of the gear rack in only one direction is a spring that contacts the distal surface of the gears of the gear rack.

9. It would have been obvious to one having ordinary skill in the art at the time of the invention to relocate the detent mechanism to contact the sliding rack rather than the thumbwheel. The relocation of the detent would be well within the skill of the ordinary artisan since the device would still be able to perform the same function of allowing movement of the gear rack in only one direction. Regarding the limitation that the means is a spring, Failla discloses that the detent is a plastic strip which clearly has the flexibility to bend and return to original position as required by the function of the detent. It is inherent that the plastic strip is equivalent to a spring.

10. Regarding claim 15, It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an anti-clotting agent into a stent

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delivery device since it is well known in the art to deliver drugs at the time of stent delivery to prevent further trauma to the tissue that is being treated.

**11. Claims 2, 6, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilson (WO 99/49808) in view of Failla (US 5,501,654) as applied to claim 13 above and further in view of Fitz (USPN 6,146,415).**

12. Gilson in view of Failla discloses the invention substantially as claimed as stated above.

13. Gilson in view of Failla does not disclose an outer sheath, which is attached to the control handle to prevent the inner catheter member from moving distally when the outer restraining member is retracted. Gilson in view of Failla does not that the guide wire lumen extends from the proximal end to the distal end of the catheter

14. Fitz discloses a stent delivery system that comprises an inner catheter (10), a restraining sheath (16) analogous to that which is disclosed by Gilson. Fitz further discloses the use of a guide catheter with a coupling member (40) wherein the proximal the position of the catheter handle with respect to the guide catheter (Col 6, line 56-62). The outer sheath is removably attached to the control handle (50). Fitz states that this feature is an improvement to stent delivery catheters because it prevents unwanted movement of the device during delivery and provides greater accuracy of stent placement. Fitz discloses stent delivery system which can be quick exchange or over the wire thereby having a guidewire lumen that extends from the distal end to the proximal end.

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15. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a guide catheter since it is well known in the art to use a guide catheter to provide a stable channel for delivering working catheters to the body. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a guide catheter with a coupling member into the stent delivery device to enhance the function of the device by ensuring accurate delivery of the stent. Fitz provides the motivation which is well within the scope of the invention. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify a stent delivery device to be quick exchange or over the wire depending on the needs of the user and the method of use. It is well known in the art to interchange over the wire catheters with quick exchange catheters. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

16. Regarding claim 16, It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an anti-clotting agent into a stent delivery device since it is well known in the art to deliver drugs at the time of stent delivery to prevent further trauma to the tissue that is being treated.

**17. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilson et al. (WO99/49808) in view of Failla et al. (USPN 5,501,654) as applied to claim 13 above and further in view of Stack et al (6,860,898).**

18. Gilson in view of Failla discloses the invention substantially as claimed as stated above except for the means for evacuating air.

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19. Stack discloses a stent delivery device. The device provides openings (49) in the catheter for allowing the evacuation of air.

20. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate flushing system including holes for evacuating air since it is well known in the art as evidenced by Stack. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

**21. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilson (WO 99/49808) in view of Failla (US 5,501,654) in view of Fitz (USPN 6,146,415) as applied to claim 19 above, and further in view of Kratoska et al. (USPN 6,183,443)**

22. Gilson in view of Fitz discloses the instant invention substantially as claimed as stated above except for "the outer sheath is attached to a strain relief member, which is removably attached".

23. Kratoska discloses an introducer sheath having a proximal end attached to a strain relief member. The introducer of Kratoska is a separate entity from the device that is being inserted into it just as in Sullivan in view of Failla. The introducer has a distal portion that has a smaller inner diameter than a proximal portion of the sheath.

24. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a strain relief into the introducer since it is well known in the art to use a strain relief as evidenced by Kratoska to reduce buckling or kinking.



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**25. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilson in view of Failla in view of Fitz in view of Kratoska as applied to claim 7 above, and further in view of Lowery et al (USPN 4,624,243).**

26. Gilson in view of Fitz in view of Kratoska discloses the instant invention substantially as claimed as stated above except for “the strain relief having a channel for receiving a tab like member of the control handle”.

27. Lowery discloses that it is old and well known in the art to use a threaded connection between an introducer and a medical device. The spaces between the threads of the introducer are analogous with the channel of the strain relief and the projecting threads of the medical device are analogous with the tabs on the control handle.

28. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate threads into the introducer and the medical device since it is old and well known in the art. Furthermore it provides the advantage of stabilizing the device while performing the medical procedure.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

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### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Todd E. Manahan  
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